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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,024

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Tetsuo Santo

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EXAMINER

CLARK, AMY LYNN

ART UNIT

PAPER NUMBER

1655

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,024	<b>Applicant(s)</b> SANTO ET AL.	
	<b>Examiner</b> Amy L. Clark	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

Claim 6 has been rejoined.

***Claim Objections***

Claim 8 is objected to because of the following informalities: please correct “licorice” to read licorice. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Chen (N, CN 1324646 A, Abstract only).

Chen teaches a pharynx-benefiting tea comprising pulverizing isatis root and licorice root into fine powder, decocting sophora root, filtering adding rock candy, concentrating the composition and mixing it with starch, boiling it into a paste, then mixing the paste with the fine powder to obtain granules.

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, *per se*, since such undisclosed use is

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inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting.

"[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims.

Therefore, the reference anticipates the claimed subject matter.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yumai Liu (O, CN 1095291 A, Abstract only), Wenjiang Liu (P, CN 1195537 A, Abstract only), Su et al. (Q, CN 1134837 A, Abstract only), Xu (R, CN 1252296 A, Abstract only), Golyuk (S, SU 917839 B, Abstract only), Gao et al. (T, CN 1077896 A, Abstract only), Huang (N1, CN 1189343 A, Abstract only), Leng et al. (O1, CN 1110163 A, Abstract only), Kolosovskii et al. (P1, SU 1793927 A3, Abstract only) and Wang et al. (Q1, CN 1146353 A, Abstract only).

Yumai Liu teaches a drug in the form of tablet, pill or instant powder for treating psoriasis, prepared from sophora root and isatis root. Liu further teaches that the composition comprises additional ingredients, wherein the additional ingredients can be arnebia root, which reads on lithospermum. Yumai Liu does not teach that the composition comprises barbat skullcap or licorice.

However, Wenjiang Liu teaches a Chinese medicine oral preparation with various dosage forms for curing psoriasis comprising scutellaria root in an amount of 10-20g, which reads on Baikal skullcap, isatis root in an amount of 10-20g, and licorice in an amount of 5-10g.

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Yumai Liu does not teach *Smilax glabra*; however, Su teaches an oral medicine for treating psoriasis comprising *Smilax glabra*, licorice root and flavescent sophora root.

Yumai Liu does not teach *Kudingcha*; however, Xu teaches a health tea comprising *Ilex*, which is synonymous with *Kudingcha*, for curing tissue damage.

Yumai Liu does not teach Japanese angelica root. However, Golyuk teaches a medical composition for treating psoriasis, wherein the composition is administered orally and wherein the composition comprises 2-4 ml *Aralia*, which is synonymous with Japanese angelica root.

Yumai Liu does not teach *Corydalis*; however, Gao teaches a medicine for treating psoriasis comprising *Radix Sophora flavescentis* and *Corydalis tuber*, wherein the medicine is made by decocting with water, which intrinsically is a tea and the composition can also be in the form of wet pills or a powder.

Yumai Liu does not teach *Oldenlandia*; however, Huang teaches a medicinal powder for the treatment of psoriasis comprising *Oldenlandia*.

Yumai Liu does not teach dried tangerine peel; however, Leng teaches a health-care beautifying powder for oral administration, wherein the powder improves the appearance and the condition of skin comprising tangerine peel, wherein the tangerine peel is dried.

Yumai Liu does not teach smartweed. However, Kolosovskii teaches an herbal remedy for oral ingestion comprising 16-19 wt. % *Polygonum* (knotweed), which is synonymous with smartweed, for treating psoriasis.

Yumai Liu does not teach peppermint. However, Wang teaches a treatment composition for curing psoriasis, wherein the treatment composition is in the form of an orally administered capsule prepared from peppermint in an amount of 20 grams.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition taught by Yumai Liu to provide the instantly claimed invention by combining lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice, which are all ingredients that have the same functional effect of treating psoriasis and other skin conditions, which are examples of dermatitis. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed ingredients of lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice for their known benefit in treating dermatitis, since each claimed ingredient is well known in the art for the same purpose, as useful for dermatitis and for the following reason:

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980); *In re Crockett*, 279 F.2d 274, 126 USPQ 186

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(CCPA 1960); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

As the court explained in Crockett, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice, are useful for treating psoriasis and other skin conditions, which are examples of dermatitis, it would have been obvious to combine these ingredients with the expectation that such a combination would be effective for treating dermatitis. Thus, combining them flows logically from their having been individually taught in prior art.

From the teachings of the references, it is apparent that one of ordinary skill in the art one would have been motivated to combine lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice to provide a beneficial composition for the expected benefit of treating dermatitis because at the time the invention was made, the instantly claimed ingredients of lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice were known to be useful for treating psoriasis and other skin conditions, which are examples of dermatitis, and since the ingredients and mode of administering the ingredients, which are one and the same as those claimed by Applicants, was known in



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the art at the time the invention was made. Thus the combined composition of lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice would have been expected to be even more effective for treating of dermatitis because the claimed ingredients were all useful for this purpose, as clearly taught by the above references.

Finally, one of ordinary skill in the art would have had a reasonable expectation of success to combine the following ingredients for treating dermatitis to gain the benefits of individual components as part of a composition for treating dermatitis: lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice, to provide a beneficial composition for the expected benefit of treating dermatitis because at the time the invention was made, these ingredients were well known treating psoriasis and other skin conditions, which are examples of dermatitis.

Moreover, it would have been obvious to one of ordinary skill in the art, one would have been motivated and one would have had a reasonable expectation of success at the time the invention was made to modify the referenced composition because it would have been well in the purview of one of ordinary skill in the art practicing the invention to pick and choose a an amount of each of the following ingredients: lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis,

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peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice and the amount of the composition to be administered because at the time the invention was made, lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice were known to be useful for treating dermatitis and the references provided herein teach amounts of the ingredients claimed and the amounts of times to administer compositions comprising these ingredients. Furthermore, it was well known in the art that doses to be administered are dependent on body weight and that the effectiveness of a composition depends upon the number of times and amount administered each day. Therefore, adjusting the amount of lightyellow sophora root, isatis leaf, Japanese angelica root, oldenlandia diffusa, smilax glabra, dried tangerine peel, wild chrysanthemum flower, corydalis, peppermint, baikal skullcap, lithospermum, kudingcha, smartweed, and licorice would have been obvious to enhance the effect of these ingredients. Finally, it would have been obvious to modify the form in which the oral composition is to be administered because at the time the invention was made, many different forms of oral administration were known to be acceptable and the form depends on whether the person to which the composition is administered can tolerate. For example, small children have a problem swallowing pills, so a liquid composition would be a better form of administration. Furthermore, all of Applicants' claimed ingredients were known at the time the invention was made to be orally administered. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

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Based upon the beneficial teachings of the cited references, the skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571)272-1310. The examiner can normally be reached on Monday to Friday between 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy L. Clark  
AU 1655

Amy L. Clark  
November 20, 2008

/Michele Flood/  
Primary Examiner, Art Unit 1655